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Legislative and Case-Law Analysis of Parallel Trade in Medicinal Products

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ABSTRACT: Although the European Union has long faced the problem of the shortage of medicines, the European Parliament resolution of 17 September 2020 on the shortage of medicines (P9_TA(2020)0228, paragraph 65) states that due to the increasing global demand for medicines and the COVID-19 pandemic, medicine shortages have become even more acute, affecting Member States' health systems and posing considerable risks to patients' health and care. The Committee on Industry, Research, and Energy, in its opinion of 16.6.2020 (A9-0142/2020, p. 36), recognizes that parallel trade can cause a shortage of medicines and calls on the Commission and the Member States to adequately address the problems of parallel trade in medicines in the EU, in order to prevent export shortages caused by considerable differences in the price of medicine between Member States. In this context, this article aims to analyze the regulations at the level of the European Union, the case law of the Court of Justice of the European Union, as well as the national legislative measures relating to intra-EU trade in the pharmaceutical market.

KEYWORDS: European legislation, Court of Justice of the European Union, parallel trade, shortage of medicines, distribution of medicines

Introduction

Parallel trade in products is a legal form of trade on the internal market. It is “parallel” in the sense that it involves products that are essentially similar to products traded through the sales networks of the original manufacturers or suppliers, but takes place outside and often parallel to those networks.

Parallel trade is a result of price differences between pharmaceutical products (see Case C-201/94 *Smith & Nephew*), e.g. when Member States fix or otherwise control the price of products sold on their markets. In principle, parallel trade creates healthy competition and price decreases for consumers and is a direct consequence of the development of the internal market, which guarantees the free movement of goods.

Although the safety and first placing on the market of medicinal products are regulated by European Union law, the principles on the legality of parallel trade in these products have been established following Court rulings (see Joined Cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure eV and the Commission/Bayer AG;* Case C-53/03, *Syfait and others/GlaxoSmithKline AEVE;* Joined Cases: Case C-468/06 *Sot. Lélos kai Sia EE*, Case C-469/06 *Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proïonton*, Case C-470/06 *Konstantinos Xydias kai Sia OE,* Case C-471/06 *Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proïonton*, Case C-472/06 *Ionas Stroumsas EPE*, Case C-473/06 *Ionas Stroumsas EPE*, Case C-474/06 *Pharmakapothiki Pharma-Group Messinias AE*, Case C-475/06 *K. P. Marinopoulos AE Emporias kai Dianomis Pharmakeftikon Proïonton*, Case C-476/06 *K. P. Marinopoulos AE Emporias kai Dianomis Pharmakeftikon Proïonton*, Case C-477/06 *Kokkoris D. Tsánas K. EPE and others,* Case C-478/06 *Kokkoris D. Tsánas K. EPE and others/ GlaxoSmithKline AEVE Farmakeftikon Proïonton;* Joined Cases: Case C-501/06 P *GlaxoSmithKline/ Commission*, Case C-513/06 P *Commission / GlaxoSmithKline*, Case C-515/06 P *European Association of Euro Pharmaceutical Companies (EAEPC)/ Commission,* Case C-519/06 P *Asociación de*

exportadores españoles de productos farmacéuticos (Aseprofar)/ Commission) under the provisions of the TFEU on the free movement of goods (Article 34).

In relation to medicinal products, where the information necessary for the protection of public health is already available to the competent authorities of the Member States of destination, following the first placing on the market of a product in that Member State, a parallel imported product is subject to a licence granted on the basis of a proportionally "simplified" procedure (different from a marketing authorization procedure), if the imported product has been granted a marketing authorization in the Member State of origin and if the imported product is essentially similar to a product which has already been granted a marketing authorization in the Member State of destination.

Theory

To ensure a balance between the rights of parallel traders and the need to support public interest objectives such as public health, the Commission introduced guidelines on parallel imports of patented medicines already authorized for marketing (COM (2003) 839 final).

In addition, a distinction must be made between parallel trade and re-import. For example, in the case of pharmaceuticals, re-importation refers to transactions whereby medicinal products are imported into a Member State where they are authorized, after having been previously obtained by a pharmacy in another Member State, from a wholesaler from the Member State of importation (Marin and Buzescu 2020, 728-737).

In that regard, the Court has held that a product manufactured in one Member State which is exported and then re-imported into that Member State constitutes an imported product in the same way as a product manufactured in another Member State (see: Case C-322/01 *Deutscher Apothekerwerband*, paragraph 127; Case 229/83 *Leclerc and others*, paragraph 26; Case C-240/95 *Schmit*, paragraph 10). The Court pointed out, however, that those conclusions do not apply if it is found that the products in question were exported solely for the purpose of re-importation with a view to evading legislation such as that in question (see Case C-322/01 *Deutscher Apothekerwerband*, paragraph 129).

Results and discussions

Parallel imports or intra-Community trade as this sector of the pharmaceutical market is also called, is based on the free movement of goods, in accordance with Articles 28 and 30 TFEU on the 'doctrine of regional exhaustion'.

At European level, the parallel distribution of medicines is managed centrally by the European Medicines Agency (EMA). According to Article 77 of Directive 2001/83/EC, for a distributor to become a parallel import authorisation holder, it must hold a valid authorisation for the wholesale distribution of medicinal products.

If the parallel importer intends to make changes in labeling, outer packaging, etc., they must have a manufacturing authorization in addition to the distribution authorization. The parallel importer must comply with the good practice rules in distribution and, where applicable, with the good practice rules in manufacturing. The parallel importer is personally liable for legal issues related to the brand of the parallel imported medicine.

At the national level, parallel importation is the operation whereby a medicine for which the Romanian National Agency has issued a marketing authorization for Medicines and Medical Devices (Agenția Națională a Medicamentului și a Dispozitivelor Medicale - ANMDMR) is introduced into Romania through distribution channels other than those agreed by the holder of the marketing authorization for that medicine. The national authority manages the parallel import of nationally authorized medicines through a "purely national" procedure or mutual recognition or decentralized procedures.

Order no. 1.962/2008 lays down certain conditions that a medicinal product must meet to be brought from another EU Member State to Romania through parallel import.

According to the Court's case-law (Judgment of the Court of October 8 2020, Case C-602/19 *Kohlpharma GmbH v Bundesrepublik Deutschland*), in order for a parallel import authorization to be issued, the applicant must submit data or arguments which make it at least plausible that the efficacy and safety of the directly distributed originator medicinal product are also applicable to the parallel imported medicinal product. In general, the efficacy and safety of the originator medicinal product are presumed to be applicable to the parallel imported medicinal product when the holder of the marketing authorization for the parallel imported medicinal product in the exporting country is the same, belongs to the same group of companies as the marketing authorization holder for the originator medicinal product distributed directly in Romania or there is a licensing agreement or other similar legal situation between the two holders.

The documentation submitted in order to obtain the Parallel Import Authorisation (PIDA) contains the same five Annexes that form the basis for obtaining the marketing authorization for any medicinal product registered in Romania.

In addition to these documents, the holder of the PIDA is obliged to notify both the marketing authorisation holder of the directly distributed originar medicinal product and the brand holder of the intention to place a medicinal product on the Romanian market through a parallel import mechanism.

Most of the time, the notifications bring about certain responses and comments from these entities. This is because the medicines subject to a parallel import authorization are medicines whose price in the source country is lower than the price of the original medicine.

The holder of the PIDA is obliged to monitor adverse effects and to report to the competent authority any adverse effect or deficiency of a medicinal product subject to a parallel import authorization. The parallel import authorization holder is also obliged to notify any other changes to the parallel medicinal product, such as changes to the qualitative or quantitative components, changes to the primary packaging or even changes to the design of the pharmaceutical shape.

The decision to grant authorization is taken by the ANMDMR based on as much information as possible, including by requesting additional information from the competent authorities of the exporting country (Botină, Marin, 57-66).

The parallel imported medicinal product may have a different name from that of the medicinal product authorized in Romania or in the country of export, subject to compliance with the legislation in force concerning the name of medicinal products. Both over-the-counter and prescription-only medicines can be subject to a parallel import authorization. In the case of intra-EU trade in OTCs, because prices are not so highly regulated, it is easy to market them as long as their prices are lower than those of OTCs distributed through the traditional distribution channel.

In the case of prescription medicines, and especially those in the National Catalogue of Prices of Prescription Medicinal Products for Human Use (Catalogul național al prețurilor la medicamentele de uz uman eliberate cu prescripție medicală – CANAMED), the procedure for obtaining the price at which they are to be placed on the market can make it difficult for health professionals and patients to access these medicines. Also, since the entry into force of Directive 2011/62/EU transposed into national legislation by Law no. 95/2006, which states that the marketing of prescription-only medicinal products will, with very few exceptions, only take place if they bear the new safety features, the holders of PIDAs are considered producers and are thus obliged to comply with the new regulations. This makes the repackaging process more difficult and leads to a significant increase in the cost of marketing the medicinal product.

To comply, when a parallel distributor imports RXs from another EU country, it must first remove the unique identifiers and decommission those batches from the database of the country of origin. These are then repackaged with new unique identifiers applied and recommended in the European Medicines Verification System.

Conclusions

In view of the benefit to the health budget, some EU countries have introduced provisions in national legislation to encourage and support parallel imports. In countries such as Denmark, parallel imported medicines account for 30% of the total sales of medicines, and in Germany at least 5% of the sales volume at pharmacy level is required by national law to be of parallel imported medicines.

The benefits of parallel imports for the state budget are that can be brought into Romania authorized medicines which are cheaper and can be supplied at a price below those already available. Parallel importation can also be a price control strategy as it gives suppliers and distributors a strong bargaining power with producers to reduce prices.

One of the most important advantages of parallel importation is the continuity of access to medicines withdrawn for commercial or production reasons or discontinued on the domestic market. Through the parallel import procedure, authorized medicines that are missing from the market can be brought onto the market, thus giving patients access to medicines that are so essential in the treatment of certain conditions.

Although at the national level, parallel import legislation is not entirely complete, the benefits for both patients and the national budget could lead to legislative changes that could solve the current crisis of medicinal products, as an alternative that could compensate for shortages in the traditional distribution channel.

In response to the emerging problem of shortages of medicines on the internal market, the European Parliament called on the Commission to assess the impact of parallel trade on the shortage of medicines in Member States and to adequately address the problems by taking the necessary measures to ensure that medicines reach all patients in the EU in a timely manner. As parallel trade sometimes covers up to 80 or 90% of the demand in some Member States, which weakens the supply chain, the European Parliament believes that parallel trade causes a discrepancy between the volume introduced by manufacturers on a given market, the volume of exports and imports and the real needs of patients on that market, which can lead to shortages.

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